UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple, Plaintiffs,	Phoenix, Arizona **September 26, 2018**
v.	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation, Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 7 - P.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

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I N D E X

EXAMINATION

EXHIBITS

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EXHIBITS

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EXHIBITS

P R O C E E D I N G S

(Proceedings resumed at 1:00 p.m. in open court with the jury present.)

13:01:41 THE COURT: Please be seated. Let's continue with the deposition.

(Video testimony of Dr. Krishna Kandarpa resumed.)

MR. LOPEZ: That concludes that testimony.

13:41:43 MR. O'CONNOR: Your Honor, at this time we're going to call Mr. Michael Randall.

MR. ROGERS: Your Honor, I understand Mr. Randall stepped out to the men's room and he's going to be right back.

THE COURT: All right.

13:41:59 If you want to stand up, ladies and gentlemen, feel free.

THE COURTROOM DEPUTY: Mr. Randall, if you'll please stand right here and raise your right hand.

MR. O'CONNOR: May I proceed, Your Honor?

MICHAEL A. RANDALL,

13:43:51 called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. O'CONNOR:

Q Hello, Mr. Randall. I'm Mark O'Connor. I think we've met

13:44:03 before.

13:44:03 A Yes, we have. Hello.
Q How are you doing today?
A Doing well. Thank you.
Q You still work for Bard; is that correct?
13:44:10 A Yes.
Q As I understand it, you've been there about 12 years?
A Yes.
Q And you are one of the directors of research and development; is that correct?
13:44:18 A That's correct.
Q And there was a period of time where you were the lead, at least for a while, for the platinum G2 project?
A Yes.
Q In research and development you work with engineers; is
13:44:33 that correct?
A That's correct.
Q You also work with other people throughout Bard at the company. Fair?
A Yes.
13:44:41 Q And you work with an engineer named Andrzej Chanduszko?
A Chanduszko. Yes, I do.
Q And Mr. Chanduszko is an engineer here in Tempe, Arizona, at the Bard facility here?
A Yes, he is.
13:44:54 Q Thank you.

13:44:54 In June 2008 you and Mr. Chanduszko conducted a meeting in which you developed an agenda and the meeting concerned the EVEREST study and MAUDE data. Do you recall that?

13:45:10 A Yes, there was a meeting held. I think we were kicking off the project for the platinum.

Q I want to show you a PowerPoint that was discussed.

MR. O'CONNOR: Felice, if you could put up Exhibit 1222. Thank you.

13:45:28 BY MR. O'CONNOR:

Q Sir, you recognize this exhibit; correct? 1222.

A Yes.

Q Pardon me?

A Yes.

13:45:34 MR. O'CONNOR: Move to admit 1222, Your Honor.

MS. HELM: No objection.

THE COURT: Admitted.

(Exhibit 1222 admitted.)

MR. O'CONNOR: May I publish, Your Honor?

13:45:48 THE COURT: Not until Traci's back.

MR. O'CONNOR: And I finally remembered.

(Courtroom deputy enters the courtroom.)

THE COURT: We can publish that, Traci.

MR. O'CONNOR: Felice, can we go to the page with the

13:46:24 Venn diagram on 1222, please. The EVEREST Venn diagram. For

some reason I missed it in my note.

Thank you.

BY MR. O'CONNOR:

Q Mr. Randall, this was included in the PowerPoint and this is what you would call a Venn, V-E-N-N, diagram?

A Correct.

Q And what this was was a way to illustrate the patients who participated in the EVEREST study and complications that were found; is that correct?

A Correct.

Q And what you did was you have circles that show within those circles the numbers of complications, including penetration, tilt, and caudal migration; is that right?

A Yes.

Q And what is also shown on this diagram is where the circles intersect. And for the benefit of the jury, that's where a filter in the study -- by the way, this was the G2 filter; true?

A Correct. It was.

Q And where the circles intersect, that will show patients who had a filter that experienced more than one complication. Fair?

A Yes.

Q And so that's how anybody that looks at this should understand that document; is that fair?

13:47:38 A Yes.
Q And so when you look at the one right in the middle, 3, there was a filter that experienced penetration, tilt, and caudal migration; true?
13:47:48 A True. And then there's an asterisk there, too. So fracture.
Q I see. You noted one of these filters had a fractured arm and had a leg proceeding -- proceeding by saluting arm and tilt.
13:48:03 Did I read that correctly?
A Yes.
Q You're referring to one of the three that experienced the other three complications; true?
A True.
13:48:11 MR. O'CONNOR: Felice, there's also a similar diagram for MAUDE.
What we were just looking at was page 6.
Thank you.
BY MR. O'CONNOR:
13:48:22 Q Also at this meeting you discussed MAUDE data pertaining to the G2 filter; true?
A True.
Q And this is MAUDE data as of January 7, 2008, regarding the G2 filter; correct?
13:48:34 A Yes.

13:48:36 Q This is separate from those patients that were followed in the EVEREST study; correct?
A Correct.
Q And here again, the same thing. The Venn diagram, the
13:48:46 circular diagram, shows that the number of complications, including tilt, penetration, and caudal migration; is that right?
A Yes.
Q And I think later in the PowerPoint those are all totaled
13:49:02 up for the jury's benefit when they read this; is that right?
A What part of the PowerPoint?
Q I think on the next page, but I may be wrong.
A You said are they totaled up?
Q No, not on this page apparently.
13:49:22 But anyway, this page goes for several -- this document goes for several pages and I want to --
MR. O'CONNOR: Thank you, Felice.
BY MR. O'CONNOR:
Q Here we go. Page 11. So, Mr. Randall, what we're looking
13:49:38 at is actually a table that totaled up complications from complaints, is that correct, from the MAUDE data?
A Yeah. I see it says "total complaints," but I'm not sure exactly how this data was dissected. I didn't put this together.
13:50:04 Q I think you said Mr. Chanduszko did.

13:50:06 A Yes, he did.
Q And it looks as though, if we look, there's a left-hand column that talks about the different types of complications; correct?
13:50:11 A Yes.
Q That's from the MAUDE data.
And then it looks as though the next column you can determine -- to read this you would see the total number of complaints next to each type of complication or failure mode.
13:50:24 Do you see that?
A Yes.
Q So, for example, in the middle column if you look at migration, caudal migration, going down, there were 61 total complaints in the MAUDE data that Bard looked at for G2
13:50:37 filters through January 7, 2008; correct?
A I think it says right here January 7, 2008.
Q And I'm looking just at the very first row up there, "migration, caudal, 61." Do you see where I read from that?
A Yes, I do.
13:50:56 Q And then if you go down, there's a next section that starts, for example, "migration and tilt." Do you see where I'm looking at?
A Yep.
Q And what Mr. Chanduszko is showing there is the
13:51:08 combination of two different types of failures in one

filter -- that is, migration and tilt -- and he has there 37. 37 total complaints. Fair reading?

A Yes. I see that. 37.

Q Then we can look at the bottom third and that will show combinations of three different failure modes, first one being migration, tilt, and perforation. Do you see where I'm looking?

A Yes.

Q And next to that, total complaints is 6. Do you see where I read?

A Yes, I do.

Q And this was, I imagine, among other things, Bard was looking at what was learned from EVEREST to look at the design of the filter and understand the failure modes that the G2 was experiencing. Fair?

A Yeah. We were looking at EVEREST data and looking at literature as well as MAUDE.

Q Thank you.

MR. O'CONNOR: Can we go to page 13, Felice.

BY MR. O'CONNOR:

Q And this was included in the PowerPoint, this statement, and I'll read it to you, and you can tell me if I read it correctly, sir. "Caudal migration, tilt, perforation, and fractures are the most commonly occurring complications associated with this filter. Eliminating these failure modes

would reduce number of filter complaints from 152 to 34." Then, it says, parens, by 78 percent.

Did I read that correctly?

A Yes, you did.

Q Thank you.

MR. O'CONNOR: Felice, can we go to Exhibit 354.

MR. LOPEZ: One more time, Mark.

MR. O'CONNOR: I'm sorry. Felice, 354. Three, five, four.

Thank you.

BY MR. O'CONNOR:

Q Now, this is a document from Bard entitled "G2 Platinum." And you were a team leader for a period of time on the G2 Platinum project; correct?

A Correct.

MR. O'CONNOR: I move to admit 354, Your Honor.

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 354 admitted.)

MR. O'CONNOR: Thank you. May I publish to the jury?

THE COURT: You may.

BY MR. O'CONNOR:

Q And if we look at this, it's entitled G2 Platinum, and that was a project that was going to develop a filter with caudal anchors; is that correct?

13:53:32 A That was one of the features that we were looking at.
Q And, sir, if we go through this document --
MR. O'CONNOR: Felice, go to page 2.
BY MR. O'CONNOR:
13:53:47 Q -- and if we look at the bottom paragraph it says "Based upon the fish bone analysis, insufficient caudal anchoring is likely the root cause of caudal tilts and caudal migrations and indirectly of penetrations and fractures."
Did I read that correctly?
13:54:24 A Yes, you did.
Q And root cause is an analysis that people do at Bard, including people in your department; true?
A Usually it's the quality function group that does that, but, yes, R&D, engineering participate in that as well.
13:54:37 Q And simply put, as I understand as a lay person, it means to look at a design and get to the bottom line of what is causing failures. Is that fair?
A We look at what's the most probable or most likely, so --
Q Thank you.
13:54:56 So when the words "root cause" are used in a sentence, it means what Bard is trying to say is here is what is most likely or most probable a cause of different types of failure modes. Fair reading? If we apply your definition to root cause.
13:55:11 A Yeah. I'm seeing right here it is likely.

13:55:15 Q Thank you.

MR. O'CONNOR: If we could go to page 5, Felice. Thank you.

BY MR. O'CONNOR:

13:55:25 Q And, again, this is again the Venn diagram.

MR. O'CONNOR: If we can enlarge it, Felice.

BY MR. O'CONNOR:

Q That was done by people like Mr. Chanduszko to show a relationship between the various failure modes including tilt, penetration, and caudal migration; true?

13:55:41 A Yes. Looks exactly like that other slide Andrzej put together.

Q And this was prepared by the people in Bard; correct?

A I'm looking at this but I don't recall the slide.

13:55:56 When you threw up the first slide and I saw that picture that said G2 Platinum, I don't recall seeing this entire document. Would you have a copy?

Q Well, you agree this looks like the slide we looked at --

A It does. Yes, it does.

13:56:12 Q And the slide we looked at in the earlier exhibit was a slide that was prepared to show the interrelationship between the failures. Fair? The other Venn diagram we looked at in the other slide show.

A Yes.

13:56:23 Q Thank you.

13:56:24 And, Felice, if we could go to page 6.

BY MR. O'CONNOR:

Q And here the same type of effort, same type of study was done, and this includes data as of August 28, 2008. Do you

13:56:41 see where I'm reading from?

A Yes, I do.

Q And, again, what's happening here is that this is looking at adverse events that are being reported that are outside of the EVEREST study or beyond EVEREST; true? TrackWise.

13:57:02 A Yes, I believe so, because it says TrackWise.

Q Thank you.

MR. O'CONNOR: Finally, if we could go to page 9, Felice.

BY MR. O'CONNOR:

13:57:17 Q And here is a statement about Bard's finding from TrackWise, and I'll read it to you, Mr. Randall: "The greatest number of complications, this is associated with tilts," paren, "104, followed by penetrations, 84, caudal migrations, 82, and fractures, 46. This is inconsistent with

13:57:41 the EVEREST data."

Now, did I read that correctly?

A You did.

Q Fair to say that after the G2, and the G2X were launched, that there were no further clinical trials testing either the

13:57:54 G2 or G2X?

13:57:55 A Correct.

MR. O'CONNOR: Felice, may we go to Exhibit 4894.

BY MR. O'CONNOR:

Q And, Mr. Randall, this document is entitled The Eclipse

13:58:26 Vail Filter System. Was Vail another way of saying Eclipse, the Eclipse filter?

A Yes. That was the internal code name for the project was Vail.

Q And do you see your signature on that page?

13:58:41 A Yes, I do.

MR. O'CONNOR: Move to admit 4894.

MS. HELM: No objection, Your Honor.

MR. O'CONNOR: May I publish, Your Honor?

THE COURT: Yes. Admitted and you may publish.

13:58:53 MR. O'CONNOR: Thank you.

(Exhibit 4894 admitted.)

MR. O'CONNOR: Felice, can we go to page 5, please.

BY MR. O'CONNOR:

Q Sir, what I'd like to do is look at 2.2.3.

13:59:44 And put this document in context. We're talking about a Bard risk analysis of the Eclipse filter; is that right?

A Yes, I believe. Yep.

Q And the top column is for -- states "Characteristics

14:00:04 Related to the Safety of the Device." Do you see that?

14:00:07 A Yes, I do.
Q At 2.2.3 it says, "Expected lifetime of implant and reversibility" and to the right it says "temporarily or lifetime."
14:00:16 Did I read that correctly?
A Yes, you did.
Q Lifetime of patient. And it directs us to paragraph 2.2.3.
MR. O'CONNOR: If we could go to page 9, Felice.
14:00:32 BY MR. O'CONNOR:
Q Sir, here again we have the two same type of columns, Characteristics Related to the Safety of the Device, and Comments. Do you see that?
A Yes, I do.
14:00:59 MR. O'CONNOR: Felice, if we could enlarge paragraph 2.23.
BY MR. O'CONNOR:
Q And on this risk analysis, Bard asked the question "What determines the lifetime of the medical device?" Do you see
14:01:14 that to the left --
A Yes.
Q -- the question?
A Yes.
Q Did I read that correctly?
14:01:23 A Yes, you did.

14:01:24 Q And the Comment section says "The intended implant duration is for the life of the patient."

Did I read that correctly?

A You did.

14:01:32 Q But it goes down in the next paragraph, says "The full lifetime of the filter has not been determined."

Do you see where I'm reading from?

A Yes, I do.

MR. O'CONNOR: Felice, can you highlight that

14:01:43 sentence.

BY MR. O'CONNOR:

Q Goes on to say, "However, this has been proven through fatigue testing that after the filter -- that the filter is safe from cyclical stresses for a period of ten years."

14:02:00 Now, did I read that correctly?

A Yes, you did.

Q But the Eclipse was promoted as a permanent filter; correct?

A Optional filter.

14:02:11 Q But it was one that was represented that could -- should be able to last in a patient for the patient's lifetime; right?

A Permanent or with the option to be retrieved.

Q I'm just talking about the permanent part.

14:02:22 A Um-hmm.

14:02:23 Q Are you with me?
A Yes.
Q And I'm reading what we just read. You are too. Do you see that?
14:02:28 A Yes.
Q Permanent, meaning the filter was intended and represented to be able to stay in the patient for the patient's lifetime if not retrieved; true?
A True.
14:02:38 Q And the filter was intended for patients of a large age group; correct? This filter was going in patients in their twenties, and their thirties, and their forties, and their fifties. That's what it was intended for, full age population.
14:02:56 A Yes. Not pediatrics, though.
Q Not pediatrics. But certainly people who had long life expectancies ahead of them.
A Yes.
Q Thank you.
14:03:21 MR. O'CONNOR: Felice, let's put up Exhibit 4895.
BY MR. O'CONNOR:
Q And, sir, do you recognize this document? It's the Meridian Eclipse Anchors Filter System Risk Analysis. Do you see that?
14:03:46 A Yes.

14:03:47 Q Is it a document you're familiar with?
A Yes, I am.
MR. O'CONNOR: Move to admit 4895.
MS. HELM: No objection, Your Honor.
14:03:55 THE COURT: Admitted.
(Exhibit 4895 admitted.)
BY MR. O'CONNOR:
Q And this was a document like the others we've seen, it was a risk analysis for the Meridian filter; correct?
14:04:06 A Correct.
MR. O'CONNOR: Felice, if we go all the way to the last page -- oh.
May I publish, Your Honor?
THE COURT: Yes.
14:04:19 MR. O'CONNOR: And can we go to the last page, please.
BY MR. O'CONNOR:
Q Just the point of this is you see that there are signatures from Bard people that are August 15, 2011. Do you
14:04:43 see that?
A Yes, I do.
MR. O'CONNOR: And then, Felice, if we could go back to the first page.
Can we go back to page 1.

14:05:13 BY MR. O'CONNOR:

Q And as we look at this page 1 of 4895, Mr. Randall, we see a figure, diagram, of the Meridian.

A Yes.

14:05:24 Q And we have talked about that throughout this trial, but that was the filter that had caudal anchors on the shoulders of the arms and on the legs. Fair?

A It was just on the arms.

Q Okay. Were there any type of anchors placed on the legs?

14:05:43 A Cranial anchors. The ones that are the same as Eclipse and previous generations.

Q Caudal anchors were placed on the arms, and that was to prevent or reduce migration downward. Fair?

A Yes.

14:05:54 Q Thank you.

MR. O'CONNOR: Felice, let's go to Exhibit 4420.

BY MR. O'CONNOR:

Q And, Mr. Randall, you recognize this document; correct?

A Yes, I do.

14:06:24 MR. O'CONNOR: I move to admit Exhibit 4420, Your Honor.

MS. HELM: Your Honor, 4420 requires redactions consistent with your prior order. So subject to the redactions and so that they're not displayed without

14:06:37 redactions, no objection.

14:06:39 THE COURT: All right. Admitted subject to redactions.

(Exhibit 4420 admitted.)

14:06:47 MR. O'CONNOR: Before I ask to publish, I would like to make sure that counsel knows where I'm going. I'm going to be looking at page 22 and 23. I don't think those are subject to any redactions.

MS. HELM: Fine.

MR. O'CONNOR: Thank you.

14:07:01 So, Your Honor, with that may I publish this to the jury?

THE COURT: Yes.

MR. O'CONNOR: Thank you.

BY MR. O'CONNOR:

14:07:10 Q And, Mr. Randall, just to keep things moving, I can represent to you but I'm happy to show you on the final page there's an electric signature by you that's dated August 15, 2011. Would that make sense to you? Or would you prefer to see it?

14:07:28 A You're saying it's on that?

Q Yes.

A If it's there --

Q It's on my copy.

A -- that makes sense.

14:07:35 Q Thank you.

14:07:36 Here again, what we're talking about is a Product Performance Specification for this Meridian filter; correct?

A Um-hmm. Yes, for the Meridian filter.

Q And just to put everything in context, the Recovery came, 14:07:47 then the G2, the G2X, the Eclipse, and then the Meridian.

A Correct.

MR. O'CONNOR: And if we go to page 23. Felice.

BY MR. O'CONNOR:

Q And, Mr. Randall, these product performance specifications 14:08:19 had a lot of different pages, categories of information, that was placed by a lot of people, including people that were responsible for testing and seeing test results; is that correct?

A I'm sorry, could you repeat that question?

14:08:31 Q Sure. There were a lot of people that had input in documents like a Product Performance Specification; right?

A Yes. Yeah.

Q People who did tests, people who reviewed test results, those type of people were included?

14:08:45 A It was not the people that conduct the test, those are usually technicians, but the cross-functional team had input on this document --

Q Certainly this was an important document for the development of the Meridian filter; correct?

14:08:57 A Correct.

14:08:58 Q And I -- it was important for anyone in Bard to be truthful and accurate in information that was placed in this document; correct?
A Correct.
14:09:08 Q So if we look at User Needs, do you see that column to the left?
A Yes, I do.
Q And it says "Filters should not migrate caudally." Do you see where I read?
14:09:21 A Yes, I do.
Q Then if we go over to the right we see bench testing, and then we go to the column Engineering Specification, Rationale, slash, Standard Reference. Do you see that?
A Yes, I do.
14:09:37 Q Pardon me?
A Yes, I do.
Q It's talking about the OptEase. Do you see that?
A For the -- the important spec one?
Q Under Engineering Specification it mentioned the OptEase.
14:09:56 A Yeah. Well, there's two migration ones so you're talking about the I.
Q I'll read this to you and just tell me if I read it correctly.
"OptEase" -- which is a competitor filter; right?
14:10:07 A Yes, it is.

14:10:07 Q Thank you. "OptEase has an acceptable clinical history of caudal migration resistance as well as a lower complaint rate for caudal migration than the G2, G2X, Eclipse.

Now, did I read that correctly, sir?

14:10:21 A Yes, you did.

Q Thank you.

MR. O'CONNOR: And then, Felice, if we could go to page 24.

BY MR. O'CONNOR:

14:10:38 Q And here again, this is an extensive document, this Product Performance Specification, but, again, we see another table that has User Needs and, and as we go across, Engineering Specification Rationale, slash, Standard Reference. Do you see that?

14:11:00 A Yes, I do.

Q And it talks about the SNF. And the SNF is the Simon Nitinol filter; right?

A Yes.

Q And the Simon Nitinol filter was the Bard permanent

14:11:05 filter; correct?

A Correct.

Q And the Simon Nitinol filter was the predicate device for the Recovery filter; true?

A I'm not sure, but I think that makes sense. That was

14:11:19 before my time.

14:11:21 Q You know what, I realized that. Fair enough. I realize you came later. So that's a fair point.

But, here, I just want to read this to you and I would just like you to confirm that I've read this correctly, 14:11:32 okay?

"SNF radial strength has been proven to be clinically acceptable as there have been minimal complaints related to perforation." And the reference is to MAUDE database.

Now, did I read that correctly?

14:11:50 A You did.

Q Thank you.

MR. O'CONNOR: Felice, can we go to page -- Exhibit 4896.

BY MR. O'CONNOR:

14:12:10 Q And, Mr. Randall, do you recognize this document?

It's entitled DV&V Caudal Migration Testing of Meridian and OptEase Filters. Do you see where I read?

A Yes, I do.

Q And what is DV&V?

14:12:34 A Design verification and validation.

Q And do you see, sir, where you signed the document August 19, 2010?

A Yes, I do.

MR. O'CONNOR: Move to admit 4896.

14:12:52 MS. HELM: No objection, Your Honor.

14:12:54 THE COURT: Admitted.

MR. O'CONNOR: May I publish?

THE COURT: Admitted. And you may.

(Exhibit 4896 admitted.)

14:13:04 BY MR. O'CONNOR:

Q We're showing this to the members of the jury, Mr. Randall. And can you tell us one more time what DV&V stands for so we can put it in the context of caudal migration testing of the Meridian and OptEase filters.

14:13:16 A Design verification and validation.

Q Thank you.

MR. O'CONNOR: Felice, I think I want to go to page 3, and I want you to go to OptEase filter, if you could, Felice.

14:13:47 Thank you.

BY MR. O'CONNOR:

Q And, again, the OptEase filter was a competitor's filter; is that correct, Mr. Randall?

A That's correct.

14:13:54 Q And I just want to read this and I want you to confirm that in this document I have read what Bard stated accurately.

"OptEase filter. The OptEase filter is retrievable up until 14 days post-implantation as directed by its accompanying IFU."

14:14:10 Did I read that correctly?

14:14:12 A Yes.

Q Thank you.

MR. O'CONNOR: And, Felice, if we would go to the next page, please.

14:14:19 BY MR. O'CONNOR:

Q And, sir, just to point out again to the members of the jury, this diagram nicely illustrates the type of anchor system that was on the Meridian; correct?

A That's correct.

14:14:40 MR. O'CONNOR: And, Felice, if you could highlight under Meridian Filter the first two sentences.

Go a couple more sentences down, Felice. I miscounted.

Actually, Felice, what I'd like you to highlight is

14:15:05 the sentence in the middle there that begins "The Meridian filter."

And the next one, too.

BY MR. O'CONNOR:

Q And this is a statement by Bard at least as early as

14:15:35 August 19, 2010, just going by your signature, Mr. Randall, and Bard states, "The Meridian filter is identical to the predicate Eclipse filter except for the addition of downward pointing titanium anchors that are laser welded to each filter arm. Six total. The addition of the downward pointing

14:15:57 anchors allow the filter to better resist caudal

movement/migration."

Did I read that correctly?

A Yes, you did.

Q And as we learned about from the earlier Venn diagram, Bard was concerned about migration and tilt and stability issues; correct?

A We looked at the filter and we wanted to make improvements anywhere we could, so we saw we could make improvements here.

Q I understand that. And this was to eliminate migration, which the intent was to eliminate other failure modes. Fair?

A We had a hypothesis that it might.

Q Fair enough.

And you were testing that hypothesis, as we saw, in documents; correct?

A I'm sorry, say that --

Q That hypothesis was being tested before the Meridian was launched. Fair?

A Well, the -- yes. It was. In testing.

Q Thank you.

And, again, the Meridian filter was launched in 2011; correct?

A I believe in 2011, I'm not sure exactly what month.

Q That's fair. But the hypotheses you had were long before 2011; correct?

A Yes.

14:17:11 Q Thank you.

MR. O'CONNOR: Exhibit, Felice, 4893.

BY MR. O'CONNOR:

Q And, sir, we've seen this type of document for other

14:17:34 filters. This is the G2 Express Risk Assessment. Do you see that?

A Yes, I do.

Q It's a Bard document; correct?

A Correct.

14:17:41 MR. O'CONNOR: Move to admit 4893.

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 4893 admitted.)

MR. O'CONNOR: May I publish?

14:17:48 THE COURT: You may.

MR. O'CONNOR: And here we go. Felice, if you could, the first paragraph, the last sentence.

BY MR. O'CONNOR:

Q And the G2 Express, again, is the G2X; correct?

14:18:12 A Say that again.

Q G2 Express is another way of saying G2X.

A Yes. Correct.

Q And the G2X was the G2 filter that had the retrieval hook placed on top.

14:18:26 A That's correct.

14:18:27 Q And what Bard stated here is the G2 Express is a permanent filter and can be optionally removed percutaneously to treat a temporary risk of pulmonary embolism. Correct?

A Correct.

14:18:40 Q That's what we talked about before. Permanent but the hope was that it could be retrieved in the short term, if necessary; right?

A Yeah. Permanent with option to retrieve.

MR. O'CONNOR: Felice, if we could go to page 4.

14:19:02 BY MR. O'CONNOR:

Q And here at paragraph 2.2.3: Characteristics Related to the Device. Here, again, Bard said about this filter, "Expected lifetime of implant and reversibility."

Did I read that correctly?

14:19:28 A You did.

Q And Bard was representing "temporarily or lifetime of patient." Do you see that to the right?

A I do see that.

Q And then if we go to page 7, and we talk about the G2X.

14:19:45 MR. O'CONNOR: And, Felice, if we could highlight 2.23.

BY MR. O'CONNOR:

Q Here again we see another question: "What determines the lifetime of the medical device?" Do you see where I'm

14:19:58 reading?

14:19:59 A Yes, I do.
Q And here again to the right, just like to the Eclipse and just like the G2, Bard stated "The intended implant duration is for the life of the patient."
14:20:18 Did I read that correctly?
A You did.
MR. O'CONNOR: Felice, can you highlight that.
BY MR. O'CONNOR:
Q And Bard said that knowing the following paragraph --
14:20:25 MR. O'CONNOR: Felice, highlight "The full lifetime."
BY MR. O'CONNOR:
Q "The full lifetime of the filter has not been determined."
Did I read that correctly?
A Yes, you did.
14:20:37 Q "However, it has been proven through fatigue testing that the filter's safe from cyclical stresses for a period of ten years."
Did I read that correctly?
A You did.
14:20:55 Q Thank you.
Let's go to Exhibit 1825.
This is an e-mail from you dated December 2, 2009, to Raji-Kubba; correct?
A Correct.
14:21:13 Q Who is Ms. Raji-Kubba?

14:21:16 A She was the VP of R&D at the time.

MR. O'CONNOR: Move to admit 1825.

MS. HELM: No objection, Your Honor.

THE COURT: Admitted.

09:25:03 (Exhibit 1825 admitted.)

MR. O'CONNOR: And, Felice, go to the next page so we can see where the chain on this e-mail starts.

BY MR. O'CONNOR:

Q This starts with an e-mail from you, Mr. Randall, to

14:21:51 people including Ms. Raji-Kubba. Do you see that?

A Yes, I do.

MR. O'CONNOR: May I publish this, Your Honor?

THE COURT: Yes.

MR. O'CONNOR: Thank you.

14:22:01 BY MR. O'CONNOR:

Q It starts here, you're telling folks on this e-mail, including Mr. Baird, Bret Baird, and Robert Carr -- we met them in the last couple days, they both work at Bard; true?

A Bret Baird no longer does but Righi does.

14:22:27 Q Oh, that's correct. Mr. Baird told us he doesn't. But Mr. Carr still does.

A Rob Carr, yes.

Q And Bret Baird was there this period, September 2009; correct?

14:22:37 A Correct.

14:22:37 Q And you say, "Here's the filter monthly report. Let me know if you have any questions. Mike."

And then above, and I'll tell you if we go back to the first page, but I think we can stay here, Ms. Raji-Kubba 14:22:51 said "Please explain why arms need to be more flexible. What did you see? Flat plate test completed. Filter arms need to be made more flexible."

So let me just put that in context for you and the members of the jury.

14:23:06 MR. O'CONNOR: Felice, we're starting at the bottom. And usually these threads kind of start from the bottom up.

BY MR. O'CONNOR:

Q So this is a response to your earlier e-mail. Can you see that? And up at the top do you see where I'm reading from, 14:23:18 from Ms. Raji-Kubba.

MR. O'CONNOR: Highlight the box up on top.

Next page, Felice.

Right there.

Can you highlight up here.

14:23:28 BY MR. O'CONNOR:

Q So this, as you can see, was coming from Ms. Raji-Kubba who said "Please explain why arms need to be more flexible. What did you see? Flat plate fatigue test completed. Filter arms need to be made more flexible."

14:23:52 Did I read that correctly?

14:23:53 A Yes, you did.
Q And then we can --
MR. O'CONNOR: Go to the first page, Felice, so we can see Mr. Randall's response.
14:24:02 BY MR. O'CONNOR:
Q And this is back to Ms. Raji-Kubba. Her name is -- do you say Abithal.
A Abithal.
MR. O'CONNOR: And the first sentence, Felice, if you
14:24:17 could highlight that.
BY MR. O'CONNOR:
Q And this is September 2, 2009; correct?
A Correct.
Q And by this time you had been at Bard for a couple years.
14:24:30 You knew from history that there had been the Recovery filter; correct?
A Yes, um-hmm.
Q And you knew there was a G2 and the G2X and that the Eclipse was going to be on the market for a period of time
14:24:41 only to be replaced by the Meridian. You knew that; correct?
A Correct.
Q And you also knew and people at Bard knew that the filter was going into the human anatomy, into the vena cava. Correct?
14:24:56 A Correct. I don't know what filter we're talking about

here, what arms, though. Because we had many projects going on.

Q Let me just read what you responded, because this is your response.

"We do not know the force that is on the vena cava that causes it to collapse."

Next sentence: "We do know it collapses. So when designing the filter, you can take two design approaches."

You talk about two approaches: Design arms so that stiffness prevents the collapse, or, design the arms so that they're flexible and can withstand the collapse. Do you see where I read?

A Correct. Yes, I do.

Q And what you're talking about are forces that are placed on the filter after it's in the vena cava; right?

A Correct.

Q And so you conclude those options with this.

MR. O'CONNOR: Last two -- two sentences in that last paragraph, Felice.

I'm sorry, the first. "Since we do not." I apologize.

BY MR. O'CONNOR:

Q You said, "Since we do not know the force, if we go with Design 1 we could negatively impact the fatigue resistance because the arms may still get collapsed if the filter is not

strong enough."

Now, did I read that correctly?

A Yes, you did.

Q And when you talk about force and you talk about collapse, you're talking about the forces that were being imposed on a vena cava filter from the vena cava itself; true?

A True.

Q Thank you.

MR. O'CONNOR: Felice, if we display 4897. Excuse me. Put that up on the screen, please.

BY MR. O'CONNOR:

Q This is an e-mail from you and it's dated August 13, 2007, to Inbal Lapid, is that how you say that name?

A Inbal Lapid.

Q That appears to be an individual at Bard you were corresponding with.

A Yes.

Q You were forwarding an attachment. Do you see that?

A Yes.

Q It was a G2 Express document, do you see that?

A The PPS. Yes.

Q If we go to the next page. This is a Product Performance Specification for the G2 Express filter systems. Do you see that?

A Yes, I do.

Q It's a Bard document?
A Yes.
MR. O'CONNOR: Move to admit Exhibit 4897.
MS. HELM: No objection.
THE COURT: Admitted.
(Exhibit 4897 admitted.)
MR. O'CONNOR: May I display, Your Honor?
THE COURT: Yes.
MR. O'CONNOR: Thank you.
BY MR. O'CONNOR:
Q And, again, Mr. Randall, I just mentioned to this. This is a document that was forwarded to another Bard individual on August 13, 2007. Do you recall where I showed you that? Correct?
A Yes.
Q And this is a fairly lengthy document, but I'd like you to go --
MR. O'CONNOR: Felice, page 37.
I'm sorry. 31, Felice. I apologize.
And that last row, 3.1.10.
BY MR. O'CONNOR:
Q And even up to 2007, even later, the Simon Nitinol filter was still relevant at Bard; correct? You were still talking about it in this document; true?
A There's a historical spec based upon that filter.

14:29:42 THE COURT: We're going to break at this point, Mr. O'Connor.

Ladies and gentlemen, we will resume at 2:45. We'll excuse the jury.

14:30:15 (Recess taken from 2:30 to 2:44. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

You may continue, Mr. O'Connor.

MR. O'CONNOR: Thank you, Your Honor.

14:46:08 BY MR. O'CONNOR:

Q Mr. Randall, I'm just going to wrap up with this document, 4897 with just this. It's a lot of pages. But, again, it states in the middle column we have enlarged, it talks about "Simon Nitinol filter radial strength has been proven to be

14:46:24 clinically acceptable." Do you see what I'm reading from?

A Yes.

Q Thank you.

MR. O'CONNOR: Felice, would you take that down and put up Exhibit 737.

14:46:34 BY MR. O'CONNOR:

Q Mr. Randall, this is an e-mail exchange between you and Ms. Raji-Kubba, do you see that at the top, and it's dated August 25, 2008.

A Yes.

14:46:54 Q All right.

14:46:54

MR. O'CONNOR: And if we go to page 2, Felice.

BY MR. O'CONNOR:

Q You see at the bottom there is an e-mail from Bret Baird, who we met earlier this week, and it goes to you and Natalie

14:47:06

Wong. Do you see that? Dated August 22, 2008.

A Yes, I do.

MR. O'CONNOR: Move to admit Exhibit 737.

MS. HELM: May I see the first page, again, please.

No objection.

14:47:19

THE COURT: Admitted.

(Exhibit 737 admitted.)

MR. O'CONNOR: May I display?

THE COURT: You may.

MR. O'CONNOR: Go to page 2, please.

14:47:29

And, Felice, if you could just highlight the e-mail from Mr. Baird, "Please join me for a conversation" all the way down.

BY MR. O'CONNOR:

Q So the e-mail looks like an invitation to meet at Bret's

14:47:51

office, and he says "Please join me for a conversation with distraught customer regarding G2. Details are below."

Do you see where I'm reading from?

A Yes, I do.

Q And he goes through a series of questions. Question 2,

14:48:07

for example, "What system is in place to monitor complication

events?" Do you see where I read that question and did I read it accurately?

A Yes, you did.

Q And then the bottom paragraph. The question above that is number 5: "How has the filter been tested to see if it can resist fracture?"

Do you see where I read, Mr. Randall? Number 5.

A I'm sorry, could you repeat that.

Q Sure. I'm reading question number 5 from Mr. Baird's e-mail --

A Okay. Yep. I see it.

Q And the answer, he goes on to state the following: "The interventional radiologists believe that there is a fundamental flaw in the material and design of the G2 based on the complications they have seen with the filter. They have been a Bard filter customer for over five years and have used the SNF, Recovery, and G2. They just switched to the Celect because of G2 filter perforation," paren, "symptomatic" and "fracture," paren, "symptomatic." We need to keep this in mind when discussing the above issues.

Now, did I read that correctly?

A Yes, you did.

MR. O'CONNOR: Thank you, I have no more questions.

THE COURT: Cross-examination.

MS. HELM: None at this time. We reserve the right

14:49:28 to call Mr. Randall in our case in chief. Thank you.

THE COURT: All right.

You can step down.

MS. REED ZAIC: Next witness will be by videotape.

14:50:10 Chris Ganser.

Chris Ganser is a graduate of the California State University in Long Beach. He earned a bachelors of science in industrial technology and quality assurance.

He began his career with C.R. Bard in 1994 and worked

14:50:26 in quality assurance. Mr. Ganser was vice president Regulatory Science at C.R. Bard from 2005 through 2006 and vice president Quality Environmental Services and Safety from 2007 through 2011 when he left Bard.

Mr. Ganser currently runs his own consulting firm and

14:50:50 consults with medical device manufacturing.

Exhibits associated with the testimony will be deposition Exhibit 516, trial Exhibit 1211.

Deposition Exhibit 517, trial Exhibit 4328.

Deposition Exhibit 522 will be trial Exhibit 2048.

14:51:15 Deposition Exhibit 523 will be trial Exhibit 1214.

Deposition Exhibit 530 will be trial Exhibit 1220.

Deposition Exhibit 533 will be trial Exhibit 1221.

Deposition Exhibit 534 will be trial Exhibit 1222.

I'd like to move these into evidence at this time although I

14:51:43 think 1222 is already in evidence.

14:51:45 THE COURTROOM DEPUTY: So is 1221.

THE COURT: And so is 1221.

MS. HELM: Your Honor, no objection except for a number of these exhibits need to be redacted subject to your

14:51:59 prior orders. So subject to that, no objection.

THE COURT: All right. They're admitted subject to redaction.

(Exhibits 1211, 4328, 1214, 1220 admitted.)

(Video testimony of Chris Ganser played.)

15:24:27 THE COURT: What are we doing, Counsel?

MR. LOPEZ: I think we're going to stop playing the tape at this point, Your Honor.

THE COURT: All right.

MR. LOPEZ: Your Honor, at this time plaintiffs are

15:24:51 going to call Suzanne Parisian.

Can we approach first?

THE COURT: Yes.

If you want to stand up, ladies and gentlemen.

(Bench conference as follows:)

15:25:27 MR. LOPEZ: I'm just paranoid. Actually, that testimony, you allowed fatalities for that initial assessment of Recovery but not migration-related fatalities. There was a comparison -- in other words, there was no relationship to cephalad migration deaths. This was about an early

15:26:04 statistical analysis --

15:26:08 THE COURT: Why are we talking about this?

MR. LOPEZ: Because I panicked that something was supposed to be redacted and it wasn't.

THE COURT: So therefore why are we here?

15:26:15 MR. LOPEZ: I'd like to finish playing it.

THE COURT: Ms. Helm, let's have you by the mic, please.

Ms. Smith, can you let her in.

MR. LOPEZ: And this was approved by both sides. 15:26:26 This cut. I'm sorry. This was approved. This was approved.

MS. HELM: Your Honor, as you can tell by all these tabs, we're trying to go through and catch all the references to Recovery migration death in the documents and deposition scripts. It looks like we didn't catch this word "fatality" 15:27:07 here and -- but my concern is it's been played. We all heard it. It was played in the courtroom. If we start it back up again, it just simply emphasizes Recovery fatalities.

THE COURT: Well, was there any objection to this?

MS. HELM: No, Your Honor, other than the agreement 15:27:24 to redact.

THE COURT: So it's appropriate to play it; right? But you don't have any objection to what's been played so far.

MS. HELM: Correct. My concern is I think they should just start with "You're going to have to ask Natalie." 15:27:37 Because --

15:27:38 THE COURT: We'll start after what's been played. We shouldn't replay anything like we did this morning --

MR. LOPEZ: I know.

THE COURT: -- replay three questions.

15:27:48 So we'll just pick it up and finish if there's no objection to the testimony.

MR. LOPEZ: To be clear, you allowed this part --

THE COURT: I understand.

MR. LOPEZ: -- as part of your ruling.

15:27:59 I won't go back and replay it. And I hope you understand that I looked at you when it was being played. And I thought better part of Valor is to stop playing that. And then I asked was that supposed to be redacted and she said yes. And I then I was told no. But --

15:28:18 MR. O'CONNOR: I don't think you're going to get a bean back. You just lost a bean.

(Bench conference concludes.)

THE COURT: Thanks, ladies and gentlemen.

We're going to finish playing this deposition and

15:28:27 then move on to Ms. Parisian.

MR. LOPEZ: Your Honor, what happened, we shut it down so I have to find out from our videographer where timewise this page/line is and it will just take me a second.

(Video testimony of Chris Ganser concluded.)

15:34:19 MR. LOPEZ: That's it, Your Honor.

15:34:28 THE COURT: All right. Let's move forward.

MR. LOPEZ: At this time plaintiffs call Dr. Suzanne Parisian.

THE COURTROOM DEPUTY: Ma'am, if you'll stand right here and raise your right hand.

15:34:40

DR. SUZANNE PARISIAN,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

15:35:16 BY MR. LOPEZ:

Q Good --

A Can you hear me? Okay.

Q Good afternoon, Dr. Parisian.

A Good afternoon.

15:35:27 Q Please introduce yourself to the Court and jury, please.

A I'm Dr. Suzanne Parisian. I live here in Phoenix. And I was -- I'm a physician and I was working at the time -- the reason I'm here is because I worked as chief medical officer at the Food and Drug Administration in the Center for Devices and Radiological Health. Since 1995 I've had a consulting business about issues related to FDA and I would explain the FDA process to all kinds of people, including in this type of setting.

Q Okay. Let's give you a little more credit than what you

15:36:07 just said and tell us about your educational background.

15:36:11 A I have an MD degree from University of South Florida in Tampa, Florida from 19 I guess 78. It's a long time ago. And then I did a flexible internship in Greenville, South Carolina. And I was a general practitioner for a while in
15:36:31 North Carolina working in an ER. Emergency room. I was also in the health department for a period of time there.

Then I went back -- after my internship I went back and did a pathology residency at U.S.C. in San Diego and U.S.C. L.A. County.

15:36:53 I was married to a husband who was a physician, too, so we were trying to put our careers together. So for a period of time I took a break, had some kids. And I went back and finished my residency in pathology in Grand Rapids, Michigan. And then I ended up at the FDA. Because of a
15:37:12 varied background, they put me in the Center for Devices and Radiological Health.

Q What is a clinical staff appointment with the Office of Medical Examiners for the Armed Forces? What was that all about?

15:37:28 A Ah. I joined -- to be part of the FDA, I joined United States Public Health Service, and if you'd seen me at the FDA, I looked like a Navy officer. I had like a Navy uniform.

And if you're in the military you have to do a clinical period of time, too, with your specialty, and so I
15:37:46 was appointed for a half day week at the Armed Forces

15:37:50 Institute of Pathology in the Office of the Medical Examiner and I was required to sign out autopsies and the final cause of death for various government employees, military people. So whatever the federal government gave me to look at in terms
15:38:08 of autopsies, I would look at autopsies.

Q Now, the title Chief Medical Officer, just generally what does that mean at FDA?

A At the FDA that means that you get not only doing your -- I was not only doing my work looking at new products and
15:38:27 products on the market, I was also required to teach others about the FDA process and to teach other medical officers how to do their jobs in terms of premarket, post-market issues.

I was involved with some agency-wide issues trying to ensure the safety of the public. That's what the FDA's to do.

15:38:49 And so as you go up and when you're chief medical officer you have more work than you would have if you were just a medical officer. So you're supervisory and at that center you're also working. So in terms of doing review --

MR. ROGERS: Your Honor, just interpose an objection.
15:39:07 I think we are moving into kind of narrative and I just want to note that for the record.

THE COURT: Go ahead, Mr. Lopez.

BY MR. LOPEZ:

Q And what is the -- in FDA there are various offices and
15:39:18 departments and things like that; is that right?

15:39:22 A Are you talking about the Center for Devices and Radiological Health?
Q Yes. What is the Office of Device Evaluation?
A Office of Device Evaluation in that office, in the FDA,
15:39:34 Center for Devices and Radiological Health Center, they look at devices that are to go onto the market.
Office of Device Evaluation is called what they call a premarket arm or office. They're looking at applications as to what a company wants to market something in the United
15:39:52 States and the people in ODE, the reviewers, look as to what can go on to the market in terms of meeting certain requirements to be marketed.
Q Would that include 510(k) products, including medical devices?
15:40:07 A Yes. That would include -- basically it's an application. It's like you're asking for a certain license, if you're a manufacturer, to begin marketing a product in the United States. And so ODE is the division that does that and they look at all of the different medical devices and it's -- but
15:40:26 it's a paper application. They don't actually look at the devices other than as the manufacturer described it.
Q Now, since leaving FDA, I think you mentioned that you were doing some consulting -- you were doing consulting work?
A Yes.
15:40:41 Q And what type of consulting work have you been doing for

the last 20-plus years?

A Yeah, I'm getting old. 1995. Since 1995 I've been consulting for various groups about anything to do with the FDA and the FDA's oversight of products, premarket issues, post-market issues would be products that are already being marketed. Safety issues.

Manufacturers, I would tell them what they need to know about the FDA. Obviously I come to clinical -- to trials like this and explain the FDA process. I've gone to medical schools and colleges and explained the FDA process. So that's basically what I discuss as a medical officer who worked at the FDA, what do people need to know about the FDA.

I wrote a book about the FDA so that people would have the history of the FDA, the entire FDA not just the Center for --

MR. ROGERS: Objection, Your Honor.

THE COURT: Let's proceed by question and answer, Mr. Lopez.

THE WITNESS: Okay.

BY MR. LOPEZ:

Q I probably should have interrupted you. I apologize, Dr. Parisian.

So as part of your consulting work that you've done, have you worked for the companies as well, medical device and pharmaceutical companies, as a consultant?

15:41:56 A Primarily medical device companies.
Q And have you also acted as an expert witness in trials that involve either medical devices or pharmaceuticals?
A Yes. And biologics.
15:42:12 Q This isn't the first time you and I have worked together on a case, is it?
A No, sir.
Q And was part of your preparation, first of all, to determine whether or not you even wanted to be an expert in
15:42:26 this case?
A That's right.
Q Did you review some material that was provided to you by me and others?
A I reviewed information that you provided. I also reviewed
15:42:39 information on my own as to what I could find in the literature and at the FDA in terms of documents. So I do my own search as to whether I want to participate in a trial or an issue in terms of either working for manufacturer, coming to something like this in terms of court.
15:42:57 Q Okay and after reviewing all of the material that you've been provided -- by the way, over what period of time have you been looking at this material that we -- that has now brought you here to share your opinions with this jury?
MR. ROGERS: Objection, Your Honor. Relevance.
15:43:19 THE COURT: Overruled.

15:43:22 THE WITNESS: I think since about 2010.

BY MR. LOPEZ:

Q So you've been looking -- and do you keep up to date with new evidentiary issues and the medical literature, things like
15:43:32 that, as part of the process you go to to give your best testimony as an expert?

A Yes, sir. And you also have to keep track of what the FDA's doing because the FDA changes. It's a government agency. So as my day to day, that's what I do. I look at the
15:43:46 FDA and then I look at all the documents I'm provided or obtain in the context of the FDA.

Q And did you prepare a report, detailed report, of your opinions, basis of your opinions, and the things that you reviewed and relied upon for your opinions?

15:44:05 A Yes, sir. I was requested to do that. Yes, sir.

Q How many pages is that report?

A I think like 253.

Q Do you have that report with you in the event you need to reference it to refresh your memory about anything?

15:44:20 A I didn't bring it up here.

Q If you need it, just let us know.

A I will.

Q Now, explain to the jury the process that medical device companies can adopt to get a device on the market without
15:44:43 going through a full, what they call, PMA.

Or a better question would have been, explain to the jury the difference between a 510(k) clearance process and a medical device going through a post -- a premarket approval process.

A Okay. A 510(k) process or application is a -- is written by the manufacturer not the FDA. And the information in the application file is basically to support to the FDA that my new device is substantially equivalent, those are the buzz words for the FDA, to a product that is already being marketed for the same intended use.

The two devices don't have to look the same, but they have to have the same intended use in terms of if -- if it's an IVC filter, a new manufacturer of an IVC filter says to the FDA I want to market a device that's an IVC filter and it's substantially equivalent to the one that's already on the market for the same use, and they also certify that there are no issues of safety and effectiveness. That if the -- if there are new issues, they're required to describe those to the FDA and provide information so the FDA can consider if there are new risks.

Q What are the -- what are the processes a company goes through in providing information to the FDA in order to establish that they want to start marketing a new device that's different than a device already on the market but that the new device is going to be at least as safe and effective

15:46:26 as what we call the predicate device?
A Well, it's up to the manufacturer to have done testing to make sure that the product, new product, is -- if you're going to claim to the FDA it's as safe and effective, you internally
15:46:40 when making the new device or going to make the new device have to do testing to make sure your statement is correct. And it's up to the manufacturer to test the device, make sure that it's going to be safe and effective for those patients and will perform the same way as they describe in their
15:46:58 510(k), and once they put it in people, use it on people, it continues to perform that same way.
Q Let me ask you this: Does the FDA create the type of test that manufacturers are supposed to perform in order to submit a 510(k) application?
15:47:18 A No. Because the -- everything at the FDA revolves around the manufacturer being the expert in that product. So the reviewers are not the expert, the manufacturer is. So the manufacturer is the one who keeps current as to the types of testing that are done and what's currently going on in the
15:47:37 industry, what you need to address in terms of the risks that have occurred with those devices. So it's the manufacturer who designs and develops the product, not the FDA, and does the right testing.
All the 510(k) is is an application saying to the FDA
15:47:54 that there should be no new risks associated with this product

and it can be used for the same intended use.

In fact, you can get a 510(k) and you don't even make the device. You're describing the device that you plan to sell and how it's going to perform once you use it in people.

Q Now, while the FDA doesn't tell the company how to test and what tests to run, does the FDA, however, have what are known as guidance documents for industry to at least reference with respect to the type of test that they might want to do for a 510(k) application?

A Well, the guidance document is really designed to tell a manufacturer as to the types of information you would put in a 510(k) that can get cleared.

The word with the 510(k) is clearance.

So to improve the quality of 510(k)s and to ensure that they were quickly cleared and able to be reviewed by the FDA, FDA puts out guidance documents as to the current best thinking in the format you would use in your application.

So it's not meant to be a cookbook for testing of a product or development but how to make an application. What you need in your application for a 510(k) to let FDA review it quickly and make a determination if you can begin marketing it.

MR. LOPEZ: Could I have Exhibit 5126, please.

BY MR. LOPEZ:

Q Is this -- do you recognize this document, Dr. Parisian?

15:49:29 A Yes, sir.
Q Is this one of the guidance documents you've been talking about?
A This is an example of a guidance document that's
15:49:36 particular for what you would use for an IVC filter.
Q Okay. Hold on.
Let me ask that this Exhibit 5126 be offered into evidence.
MR. ROGERS: No objection, Your Honor.
15:49:49 THE COURT: Admitted.
(Exhibit 5126 admitted.)
MR. LOPEZ: May I publish, Your Honor?
THE COURT: Yes.
BY MR. LOPEZ:
15:49:55 Q We're not going to go into this document, we just don't have the time right now. But this is -- when you mention a guidance -- there's actually a guidance document specific for IVC filters at least as of 1999 correct?
A And of the devices that actually were being sold in 1999
15:50:10 it was the -- FDA lists this is our best thinking at this time but technology can change. So it's not a requirement, it's a guidance, that's why they call it guidance, for submission of a 510(k) submission.
So they're telling -- it's very focused on a 510(k)
15:50:28 application and what you need to put in it.

15:50:30 Q All right.

A But it's not testing.

Q I'm sorry.

This predated the advent of permanent filters that

15:50:37 had an option for retrieval?

A Right. This is based on all the information the FDA had about permanent filters in 1999. So we're long before there's other retrievable filters.

Q So all of the testing that may be suggested in a guidance

15:50:54 document or all of the testing that a company may have done in an effort to show substantial equivalence between the device they want to start selling compared to the device already on the market, do the actual test results and actual tests that the company does, does that get submitted to FDA?

15:51:17 A No.

Q What gets submitted to FDA?

A Usually a summary saying we passed this test, we passed this test. So it's basically to make a document with a summary. So the FDA doesn't re-review all of the information

15:51:30 because the company, as the expert, should know if indeed what they're saying is correct.

Q So are the companies basically on the honor system? However they're going to represent what happened in the testing, the summary that they submit to the FDA for 510(k)

15:51:48 clearance is truthful and accurate?

15:51:51 A Yes. They have to actually sign a statement. The FDA won't accept a 510(k) without the company signing off on a statement's truthful and accurate statement saying no material facts are not present. So the FDA reviewer, because --

15:52:08 MR. ROGERS: Objection, Your Honor, I think we're moving beyond the question.

THE COURT: Sustained.

Let's proceed by question and answer.

THE WITNESS: Yes, Your Honor.

15:52:16 BY MR. LOPEZ:

Q Okay. Now, as part of the process you went through for this case, you actually looked at some of the 510(k) submissions. And I promise you and the jury we're not going to go through every single one of those, but I want to look at

15:52:28 least at a representative one.

Did you go through the 510(k) submissions of the Recovery, the G2, G2X, and the Eclipse filters?

A Yes, sir.

MR. LOPEZ: And do we have trial Exhibit 5190,

15:52:46 please.

BY MR. LOPEZ:

Q Is this the copy of the 510(k) submission you reviewed for the Recovery filter?

A Yes, sir.

15:53:03 Q And before we get into that, as far as part of your review

15:53:08 and analysis and evaluation, did you also look at a study that was conducted by Dr. Murray Asch?

A Yes, sir.

Q And did you also -- what else -- tell the jury what else

15:53:19 you did to learn more about what happened with respect to that study.

A I looked at the data that the company had internally for the study, different discussion groups that the company had about the study. I also looked at the Simon Nitinol 510(k)s,

15:53:34 too, which would be the comparison. So I looked at everything that I could find around these filters.

Q And going through the -- what you reviewed with respect to Dr. Asch, his study, did that study have anything to do with whether or not the Recovery device was substantially

15:53:56 equivalent as a permanent device to any other device on the market?

A It wasn't designed for that. It was primarily a retrievable device. I think two patients actually did leave in their device. But it was provided as data, human data, to

15:54:10 the FDA to support use of the filter. But it wasn't designed as a permanent study. It didn't compare the filter to the Simon Nitinol.

Q If Bard had represented in this application that the Asch pilot study established substantial equivalence as permanent

15:54:35 device, would that have been truthful and accurate?

15:54:39 A It would not have been consistent with the design of the study.
Q And do you know whether or not the application we're seeing here, Exhibit 5190, whether there was a truth and
15:54:57 accuracy statement signed by a representative of Bard as to all of the details that were contained within that submission?
A Yes, sir, there was.
MR. LOPEZ: Can we have Exhibit 5177, please.
BY MR. LOPEZ:
15:55:26 Q Dr. Parisian, do you see what's on your screen?
A Yes, sir.
Q Just what is that? Don't read it because it's not in evidence yet, but just describe what that is.
A It's a regulatory document about the Recovery filter and
15:55:40 the clearance.
Q Okay.
MR. LOPEZ: I'd like to move 5177 into evidence at this time.
MR. ROGERS: No objection, Your Honor.
15:55:48 THE COURT: Admitted.
MR. LOPEZ: May I publish -- I'm sorry. I stepped on your line. I apologize.
THE COURT: You may.
MR. LOPEZ: Thank you.
09:25:03 (Exhibit 5177 admitted.)

15:55:54 BY MR. LOPEZ:

Q So this, just looking at this, this is the document that FDA, after they've looked at what Bard submitted for substantial equivalence, this is what Bard gets back from FDA

15:56:08 once the device is cleared?

A This -- this letter is a 510(k) clearance letter that permits the marketing of the product. Yes, sir.

Q Now, the language that's contained in here, except for maybe the specifics about the name of the product, is this the

15:56:28 language that you've seen in the other 510(k) clearance letters for the G2, G2X, and the Eclipse?

A Yes, sir, at various times. This was when it was a permanent filter so there is a restriction in this letter that is unique to this application.

15:56:43 MR. LOPEZ: Felice, would you mind blowing up the first paragraph.

BY MR. LOPEZ:

Q So would it be fair that this is -- the FDA had determined by having looked at whatever it was that Bard submitted that

15:57:05 the device was substantially equivalent and it states right there "for the indications for use stated in the enclosure." Correct?

A Yes.

Q "To legally marketed predicate devices marketed in

15:57:21 interstate commerce prior to May 28, 1976."

15:57:24 Did I read that correctly?
A Yes, sir.
Q Is there any indication -- well, let me ask it differently.
15:57:34 Is this a determination by FDA that the device that the company is about to sell is safe and effective?
A No. It's just substantially equivalent.
Q And it's substantially equivalent based on summary of nonclinical material sent to FDA, other than the
15:57:56 retrievability clinical material sent to FDA; correct?
A Yes.
Q And then it says right below there, starting with the fourth line from the bottom: "You may therefore market the device subject to the general controls provisions of the Act
15:58:13 and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and alteration."
15:58:30 Did I read that correctly?
A Yes.
Q So even though FDA has cleared this device, is FDA making it clear to whoever the manufacturer is that once they start marketing the device, they have to adhere to what's stated
15:58:43 there in the first paragraph of the clearance letter?

15:58:47 MR. ROGERS: Objection. Leading.

THE COURT: Overruled.

THE WITNESS: Yes, that's what they're informing the person who gets the 510(k) letter. Yes, we've cleared you to 15:58:57 begin your marketing, but you have to adhere to all of these other requirements for your device to sell it in the United States.

BY MR. LOPEZ:

Q Are there actual federal regulations that require what's 15:59:09 stated in the first paragraph of the clearance letter?

A Yes, sir.

Q Do the companies have to adhere to the federal regulations and the mandates of the clearance letter without the FDA subsequently telling them they have to do that?

15:59:26 A Well, yes. It's the condition for your clearance. Clearance is that you're going to adhere to these other controls, which includes labeling, marketing, and what you state about your device. So, yes, those are the requirements to market a device in the United States.

15:59:43 Q So do the mandates of this clearance letter as we see here in the federal regulations that these refer to, do they have to be adhered to by companies irrespective of whether or not the FDA is taking some kind of action against them based on whatever information the company may have sent to the FDA?

16:00:08 A Yes --

MR. ROGERS: Objection. Leading.

THE COURT: Overruled.

THE WITNESS: Yes, it's their duty.

So they're saying, basically, these are the duties of a person who wants to sell a product in the United States, that you have to adhere to all these factors. It's not the FDA's job, it's the company's job.

BY MR. LOPEZ:

Q Let me give you an example. If FDA submits a clinical data to FDA --

A You mean a company?

Q I'm sorry. What did I say?

A If FDA.

Q Okay. I'm tired. It's a long day.

If the company submits clinical data to the FDA, and it's actual data showing complications with the device, and the company has already determined from that data and their tracking and trending of the data that the device is not substantially equivalent to the predicate device and they send that to FDA and FDA doesn't tell them you're selling an adulterated or misbranded product, is the product still adulterated and misbranded?

MR. ROGERS: Objection, Your Honor. First we have a disclosure issue and also it's a leading question.

THE COURT: What's the disclosure issue?

16:01:21 MR. ROGERS: Your Honor, I don't believe this opinion has been disclosed.

MR. LOPEZ: Your Honor. There's adulteration and misbranded all over her report. I mean, I can show it to you.

16:01:32 MR. ROGERS: I agree, Your Honor, but I believe there were multiple things all built up in that --

MR. LOPEZ: You know what, let me rephrase the question.

THE COURT: All right.

16:01:40 BY MR. LOPEZ:

Q If the company shares data with FDA that is data that the company has determined would put them in the category of the device being misbranded or adulterated, does the company have to wait for FDA to tell them to take action under those

16:02:05 circumstances?

A No. If the company's aware of that, they shouldn't sell the product.

Q If the FDA receives information and they don't take any action, is that an indication -- should that be an indication

16:02:17 to the company that the FDA has condoned them selling an adulterated or misbranded device?

A No. The manufacturer's responsible, not the FDA.

Q Now, let's -- on just a little bit more about the 510(k) process.

16:02:41 First of all, who chooses the predicate device?

16:02:45 A Manufacturer. They write the entire application and provide it to the FDA.
Q And is there something about the 510(k) process that's attractive to companies, as opposed to going through a PMA
16:03:01 process?
A It's a lot faster and a lot cheaper.
Q In order to use the 510(k) process, you just have to identify a device that's already being legally -- quote, legally marketed; correct?
16:03:16 A You have to have a predicate.
Q Predicate device. Okay.
Now, let's stick with the 510(k) medical device. Does the FDA even get to see the devices, the predicate device and new device that the company wants to market?
16:03:33 A No. It's based on paper.
Q Do they do any -- if they look at the testing and they want to question the testing, does the FDA have the facility to retest this device for the company or is that something the company would have to do?
16:03:48 A That's the company's. The FDA doesn't have -- doesn't test PMA -- 510(k) products. That's not their job.
Q Okay. Now, when you're dealing with 510(k) applications, is there someone who reviews that and then, after having reviewed it, makes a recommendation on whether or not it
16:04:09 should be cleared?

A Yeah. There's a reviewer.

Q Is that person a medical doctor or clinician most of the time?

A Majority of the time, no.

Q Give us an example -- you saw some of the records, I think, from -- that were produced on the Recovery and other filters.

A Right.

Q Give us an example of the -- I'm not meaning this to demean these people. But these are the people that are looking at 510(k) applications who are not medical doctors, so just give us an example --

THE COURT: You can't give that kind of introduction, Mr. Lopez. Let's just have you ask the question.

MR. LOPEZ: All right. I will do that, Judge.

BY MR. LOPEZ:

Q Give us the type of -- the type of qualifications and background, experience, professions of some of the people that are looking at 510(k) applications to determine whether or not they're substantial equivalence to a predicate device.

MR. ROGERS: Objection. Disclosure.

THE COURT: Is that in the report?

MR. LOPEZ: Yes.

THE COURT: Can you show me where?

MR. LOPEZ: Can you tell me where it is?

What part exactly are you talking about?

MR. ROGERS: I don't know. I'm not aware --

THE COURT: Qualifications of the reviewers.

BY MR. LOPEZ:

Q In the report you do name specifically by name; right?

A Right.

Q And I'm just going to tell you -- we can go find it in the report if you want, but do you name specifically the names and the background of some of the people that actually looked at some of these 510(k)s?

A Right. The primary reviewer through most of them is a microbiologist.

Q What's his or her name?

A She's a woman and I forget what her name is. But she's not clinical. That's -- the issue -- there's very few clinical people in the FDA Center for Devices. They don't typically review 510(k)'s primarily.

Q There was some testimony in the case about the IFU and I know you talked about the IFU in the report. Tell us, who's responsible for the IFU?

A The manufacturer.

Q Who writes the IFU?

A The manufacturer.

Q Does the FDA co-author IFUs on 510(k) devices?

A No.

16:06:36 Q Have you ever heard that before?
A No.
Q Do the FDA, when they get these new designs of a 510(k) device, have anyone there that could look at it to make the
16:06:56 determination whether or not that device might cause safety problems if it's placed in the patients?
MR. ROGERS: Objection, Your Honor. Disclosure.
THE COURT: Overruled.
THE WITNESS: No. It's primarily a nonclinical
16:07:10 reviewer. That's why they rely on the company, who's the expert, to tell the reviewer what they need to know about the product and the safety.
BY MR. LOPEZ:
Q And how about the marketing of the device. The FDA
16:07:25 doesn't give advice to companies about how to market a 510(k) device, do they?
A That's not part of the 510(k). The FDA can give advice but that is not part of the 510(k). That is part of the general controls that the letter said that the manufacturer is
16:07:41 responsible for labeling. That would be your marketing. So that's the company who does that, not the FDA.
Q So now the device has been cleared and after the device is cleared we already see that there's some language here in the clearance letter -- can we take that down.
16:08:11 Is there also other language in this clearance letter

16:08:14 that tells the company that's going to be marketing this device what their duties are under the federal regulations and what FDA's expectations are?

A Well, yeah. The paragraph we were looking at just a 16:08:28 second ago, those were all post-market issues in terms of good manufacturing practices. That would be the product you make is made within good manufacturing practices, you ensure it's safe. There's requirements to look at complaint files, to do statistical trending. That's part of the post-market part.

16:08:46 The labeling is your label, but you have to keep it updated, you have to keep adding to it.

You have to also look at adverse event reports, see if you need to update your warnings.

So that one paragraph is not just for marketing, it's 16:08:59 also for after you started marketing, that you need to keep all of this information up.

So it's not the FDA who does that. They're telling you as a manufacturer, okay, you're cleared. Now, you as manufacture, you have this duty to fulfill all these roles to 16:09:16 ensure your product is safe and effective and adequately labeled as it's now getting used in human beings.

Q We also heard testimony in this case that the FDA somehow gets involved in marketing brochures with medical device companies who are cleared through the 510(k) process. Have 16:09:36 you ever heard of that happening?

16:09:38 A That's not --

MR. ROGERS: Objection, Your Honor. Disclosure.

THE COURT: Is that in the report, Mr. Lopez?

MR. LOPEZ: Pardon me?

16:09:43 THE COURT: Is that in the report? There's a disclosure objection.

MR. LOPEZ: What is in the report is the company's responsibility --

THE COURT: Just show me in the report --

16:09:53 MR. LOPEZ: I can't, Your Honor. It's 254 pages.

THE COURT: Then let's move on.

MR. LOPEZ: Okay.

BY MR. LOPEZ:

Q Who's responsible for monitoring the clinical performance

16:10:07 of this device once it's on the open marketplace?

A The manufacturer. That's part of good manufacturing practices. You have complaint files, you're following up on how the product behaves, you're trending, and also filing adverse event reports with the FDA under 21 CFR 803.

16:10:27 So you have this continuing duty. You get it cleared, but you have all these other duties you have to keep doing as a manufacturer because you're selling the product, not the FDA.

Q What if clinically, after the device has been cleared, the

16:10:54 new device, the new product, 510(k) product, does not perform

16:10:59 as safe and effective clinically as the predicate device? What are the responsibilities of the device manufacturer under those circumstances?

A If you -- say you're cleared and your product is not performing as stated in the cleared 510(k), then that's not the product that you've gotten cleared. So you adulterated and misbranded. And typically manufacturers will either send out a warning to physicians, tell their sales reps that you need to tell doctors about the potential risk, or recall the product from the market because it's not performing the way it's supposed to and it wasn't the product that was cleared by the FDA for marketing.

And that's -- that also ended -- that end of the paragraph when it talks about adulterated and misbranded, if you have a product that's not performing as it's cleared, then you have an adulterated and misbranded product you need to remove from the market because it's prohibited to sell that product in the United States.

Q Now, if the FDA has that same data, in other words it's been submitted to the FDA and it's in an FDA database, is the company relieved of their responsibilities under that adulteration section just because the FDA is not knocking on their door and telling them they need to follow that regulation?

A No. No. The responsibility for the product rests with

16:12:21 the manufacturer. The FDA may get involved at some later point, but it is always the manufacturer's duty if they're selling the product.

Q Okay. Let's continue with this 510(k) clearance letter.

16:12:35 MR. LOPEZ: Could you just show the second half, I guess, of the body of that letter, Felice. Thank you.

BY MR. LOPEZ:

Q So what is the Office of Device Evaluation? Is that the 510(k) --

16:12:51 A That would be a branch in the Office of Device Evaluation, that would be the premarket office that's looking at this application, and the reviewer had determined -- and this is unique. This isn't always seen in 510(k)s. There is a reasonable likelihood that this device will be used for an

16:13:09 intended use not identified in the proposed labeling and that use could cause harm.

So the FDA is requiring as a condition for approved clearance that the labeling and all promotional materials in the Precaution section has the statement that the retrieval or

16:13:32 temporary filter for the Recovery has not been established. So the FDA can ask that at that time in terms of a condition for clearance.

Q So the first clearance of the Recovery filter was as a permanent device.

16:13:45 A Right.

Q And then this is talking about the fact that it cannot be used as retrievable device or hasn't been cleared that way?

A Yes.

Q And the G2, was that -- when it was first cleared by FDA, was that cleared as a permanent device?

A Yes.

Q And then later it got cleared for retrievability?

A Right, and it had a similar statement.

Q Okay. We're going to go down through this letter here in a second, the next page. But the G2 filter, when it was first cleared, did you see any evidence in the material that you reviewed that Bard had originally said that the device should be safe and effective as one predicate but because it wasn't it changed to a different predicate?

MR. ROGERS: Objection, Your Honor. Disclosure.

THE COURT: Mr. Lopez.

MR. LOPEZ: Yeah, I don't have that page right now, Your Honor.

THE WITNESS: Can I ask a clarification?

THE COURT: No. The question's not pending.

Sustained.

MR. LOPEZ: Okay.

BY MR. LOPEZ:

Q What was the predicate device that was used by Bard to clear the G2 filter as a permanent device?

A The Recovery filter --

Q I'm sorry --

A The G2. And originally in terms of the testing they were going to use the Simon Nitinol. And then when it failed to make that, they went with the Recovery.

MR. ROGERS: Objection, Your Honor, we're going beyond the question that's posed.

THE COURT: Sustained.

BY MR. LOPEZ:

Q If -- we have the Recovery filter that uses the Simon Nitinol filter as a predicate device. You've already testified to that; correct?

A Right. Yes, sir.

Q And through the multiple iterations that occurred until we get to the Meridian device and Eclipse device, they used -- did they all have to, as a matter of federal regulations, still be substantially equivalent to the original predicate device from a safety and effectiveness standpoint?

A Based on their use of substantial equivalence. If your Recovery is substantially equivalent to a Simon Nitinol and then you say your G2 is substantially equivalent to a Recovery, then you piggyback. And so they all need to say -- they all have to be correct and so therefore it would continue to be substantially equivalent to the Simon Nitinol.

Q So if a company was looking at their internal clinical

16:16:29 data that they have regarding the performance of any of these devices, determine whether or not it was still performing in compliance with the reason they got cleared, would they all -- should they all be looking at the Simon Nitinol filter for 16:16:43 that comparative safety and effectiveness standpoint?

A Yes. You shouldn't be any worse. You should be at least substantially equivalent and equivalent to that first device. You can be better, but you can't be worse.

Q Well, let's assume they're better -- let's assume the 16:17:00 Eclipse filter is better than the G2X filter, which was the predicate for the Eclipse. But the Eclipse filter is less safe and effective than the Simon Nitinol filter.

Does this device still have to be substantially equivalent to the Simon Nitinol filter in addition to its 16:17:25 predicate the G2X?

A Yes, as a permanent filter. If that's what you're claiming, you need to be substantially equivalent.

Q Does the clearance for marketing of these devices relieve the company of selling the safest and most effective device 16:17:44 they can possibly design and manufacture?

A No. It's prohibited to sell a product that's not safe and effective. So clearance allows you to begin marketing, but it's up to you to make sure you sell a product that's safe and effective.

16:17:58 Q If the company determines there are some labeling problems

16:18:03 or some design problems with their device, what is their obligation in the post-marketing phase of this device?

A Well, to ensure the safety of the public. And so if you know that you have a potential risk, you have a couple of 16:18:20 options. You can warn, you can notify the physicians, you can notify the FDA that you're going to recall the product. But -- you have options, but the bottom line is protecting patients.

Q Does the FDA involve -- in a 510(k) device like this 16:18:44 involve themselves in evaluating on their own the design attributes of a medical device?

A No. I mean no, because they're looking at every medical device that comes in the country. They'd be looking at over nine manufacturers of filters. So they're basically looking 16:19:00 at a marketing application, what the company says. And they have a certain time frame that they need to get the application done.

Q If the FDA is not questioning a company like Bard about the -- their design of their product, should that be an 16:19:21 indication to Bard that their design is appropriate and not defective?

MR. ROGERS: Objection, Your Honor. Goes beyond the *Daubert* order.

THE COURT: Hold on just a minute.

16:19:32 I don't think that question does. Overruled.

16:19:51 MR. LOPEZ: Do you have the question in mind?
THE WITNESS: I forgot it.
MR. LOPEZ: Can I ask the court reporter to read it?
THE COURT: Yes, you can.
16:19:58 (The following question was read: "If the FDA is not questioning a company like Bard about the design of their products, should that be an indication to Bard that their design is appropriate and not defective?")
THE WITNESS: No. And if you're talking about the
16:20:28 Office of Device Evaluation, they only look at the premarket application and it would be a whole other division that would eventually get involved in the post-market issues. So no. Has nothing to do with the device itself. The performance in people really is the important key once you're using this
16:20:45 product.
BY MR. LOPEZ:
Q Let's go to the next page of this clearance letter.
On the first paragraph, are those just more conditions that the company -- the FDA's placing on Bard with
16:21:08 respect to the marketing of this device?
A Yes.
Q Don't go into detail yet. We'll just go down. I want to set forth what's in the letter.
So the next paragraph.
16:21:26 And let's go down to the next paragraph, please.

"Please note the above labeling limitations are required," and then it gives the section of the Act, "therefore a new 510(k) is required before these limitations are modified."

That's talking about retrievability; correct?

A Yes, sir.

Q Let's go down to the very last paragraph.

And this is -- what does it mean when the FDA says, "Please note the regulation entitled Misbranding by Reference to Premarket Notification" in that code section?

A You can't say, represent, that the FDA has cleared my product or approved it or somehow -- so that's what it's saying. You can't refer in your marketing to the status of the FDA premarket. So you can't make statements tying the product to the FDA.

Q What is a product recall under the regulations?

A A product recall would be -- there's two sides. There's mandatory and voluntary. 99 percent are voluntary performed by industry. 21 CFR 806. And it would be removal of a product that's not safe, that does not fulfill the way it was cleared to perform. If there are safety issues that develop with a product, then a manufacturer can recall a product, remove it from the market. And the recall also involves some type of notification to the FDA that they're recalling the product. And usually either the distributors or the

16:23:03 physicians or the patients, different levels, you would notify them about the risk, you would also notify your own sales reps that you're recalling this product because of safety issues.

Q And is there actually a federal regulation that defines what a recall is or when a company should recall or stop selling a device?

16:23:22 A The process is your 21 CFR 806. And then once a company recalls a product, then the FDA goes through and classifies the risk of the recall and what needs to be done under 21 CFR part 7. So there's a process.

16:23:42 Once the FDA is told the product is being recalled, then you have a process to remove it and to ensure that the product's not used. And so it sets up a chain of events at the FDA.

16:23:59 MR. ROGERS: Your Honor, may we approach?

THE COURT: We only have five minutes left.

MR. ROGERS: Understand, Your Honor.

THE COURT: All right.

MR. ROGERS: I don't think it will take long.

16:24:08 If you want to stand up. We're going to do this quickly, ladies and gentlemen.

(Bench conference as follows:)

MR. ROGERS: Your Honor, there's no failure to recall claim in this case. That's what I understand is being laid

16:24:34 here, that she's going to testify Bard should have recalled

this product. There's no claim pending from a post-marketing standpoint that Bard failed to recall this product and they should have. We've got a design defect case.

THE COURT: Therefore?

MR. ROGERS: And therefore I think all of this is irrelevant and shouldn't be discussed in front of the jury.

THE COURT: Where are you going with failure to recall?

MR. LOPEZ: I'm not going to ask her whether or not -- I'm going to ask a company's -- just what I asked her: What are the company's responsibilities.

THE COURT: Are you going to go further on recall?

MR. LOPEZ: No, I'm not going to ask whether or not they should have.

THE COURT: All right. I think that addresses the issue.

MR. ROGERS: That's fine. Thank you.

(Bench conference concludes.)

THE COURT: Thank you.

BY MR. LOPEZ:

Q Dr. Parisian, we just talked -- there's actually a federal regulation that describes a recall when a company should exercise that obligation.

A Right.

Q Okay. And is there also a federal regulation that talks

about what -- the difference between -- well, not difference. What an enhancement is compared to a recall?

A The discussion of the recall discusses what you would recall. There is a recent guidance document that talks about enhancements for industry in order to clarify what has been the procedure at the FDA for enhancements.

Q Now --

MR. ROGERS: Objection, Your Honor. Not disclosed.

MR. LOPEZ: It is. We're finding it right now.

THE COURT: Let's move on.

MR. LOPEZ: Okay.

Well, I want to talk about enhancements, so I -- we can show you the report.

Page 208, 213, and paragraph 613.

THE COURT: Well, page 208 I see that --

MR. LOPEZ: Paragraph 218?

(Plaintiffs' counsel confer.)

THE COURT: Page 208, Mr. Lopez?

MR. LOPEZ: Hold on.

I must have my notes wrong, Your Honor. I can't -- you know --

(Plaintiffs' counsel confer.)

MR. O'CONNOR: Top of 208.

THE COURT: This is talking about specific actions of the defendant.

MR. LOPEZ: Right.

THE COURT: Not about the general subject of enhancements.

MR. LOPEZ: Right, but this -- she talks about enhancements in this paragraph.

THE COURT: Well, if you ask what's in the paragraph, then I'll overrule the objection.

BY MR. LOPEZ:

Q What is an enhancement?

A An enhancement --

MR. ROGERS: Objection, Your Honor.

THE COURT: Sustained.

MR. LOPEZ: Okay. She can't define what's in her report, Your Honor?

THE COURT: It's got to be in her report.

BY MR. LOPEZ:

Q Did you look at the EVEREST study?

A Yes, sir.

Q Did you look at the representations that were made to FDA in the EVEREST study?

A Yes, sir.

Q There was clinical data -- was there clinical data in what was submitted to the FDA?

A Yes.

Q And was there clinical data that actually talked about

some of the adverse events from the EVEREST study?

A Yes, sir.

Q What was the purpose of the EVEREST study?

THE COURT: Well, let's start tomorrow with that question. We've reached 4:30.

We will break for the day, ladies and gentlemen. Please remember not to do any research or discuss the case, and we'll see you tomorrow morning.

(The jury exited the courtroom at 4:30 p.m.)

THE COURT: Counsel, do you want to give me time allocations for the depositions today.

MS. HELM: Your Honor, for the plaintiff it's 1 hour and 56 minutes. For the defendants it is 54 minutes.

THE COURT: And that is for all six depositions played today?

MS. HELM: Yes, Your Honor.

THE COURT: All right. What was defendants' again? 54?

MS. HELM: 1 hour 56 for the plaintiff; 54 for the defense.

THE COURT: Does that sound right to Plaintiffs' counsel?

MS. SMITH: That's correct.

THE COURT: Okay. Give me just a minute.

All right, Counsel. As of the end of today

16:32:51 defendants have used 25 hours and 41 minutes -- I'm sorry. Plaintiffs have used 25 hours and 41 minutes. Defendants have used 8 hours and 42 minutes.

Anything we need to address before we break?

16:33:11 MR. LOPEZ: Not from us, Your Honor.

MR. ROGERS: No, Your Honor.

THE COURT: Okay. See you in the morning.

MR. ROGERS: Thank you.

(End of p.m. session transcript.)

16:33:21 * * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 27th day of September, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter